UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,083	06/20/2003	George E. Barringer JR.	3551.1005-000	7061

21005 7590 05/10/2006

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.
530 VIRGINIA ROAD
P.O. BOX 9133
CONCORD, MA 01742-9133

EXAMINER	
BOWERS, NATHAN ANDREW	

ART UNIT	PAPER NUMBER
1744	

DATE MAILED: 05/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/601,083	BARRINGER, GEORGE E.	
	Examiner	Art Unit	
	Nathan A. Bowers	1744	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-46 and 49-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *49-51* is/are allowed.

6)☒ Claim(s) *26-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1) Claims 26-29, 36, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newberg (US 5296197) in view of Witte (US 5948998).

Newberg discloses a method for aseptically sampling a biofluid comprising automatically collecting a biofluid sample by opening an inlet valve (Figure 2:2) at a biofluid source site (Figure 1:53). The sample is directed to a biofluid process site (Figure 2:94) by opening an outlet valve (Figure 2:93) coupled to the process site. A waste valve (Figure 2:97), coupled to a sampling conduit (Figure 2:14) and a waste site (Figure 2:98), is closed to ensure that the sample moves to the process site. This is disclosed in column 3, lines 20-46, column 6, lines 34-48, and column 10, lines 54-62. The biofluid sites are isolated by closing the inlet and outlet valves (column 13, lines 8-37) when the waste valve is opened. Column 5, line 43 to column 6, line 33 teach that the sampling conduit is cleaned before sample collection by directing a wash fluid through the inlet valve and subsequently through the waste valve to the waste site. In column 12, lines 19-52, Newberg teaches that all the valves and system operations are automatically regulated by a computer control means. Newberg, however, does not expressly disclose a trap located at the sampling conduit and fluidly connected to the waste valve, or that the biofluid is drained from the sampling conduit to the waste site.

Witte discloses a sampling device for taking sterile samples of a biological fluid. In column 1, line 13 to column 2, line 10 and in Figure 1, Witte discloses that it is well known in the art to draw a sample through a sampling conduit from a biofluid source site to a biofluid process site (Figure 1:14). Multidirectional valves (Figure 1:24) serving as both outlet valves and waste valves are also well known in the art, and, according to Figure 1, are capable of either directing fluids to the biofluid process site or to a waste site. A trap (Figure 1:36) is provided in connection with the sampling conduit and in fluid communication with a waste site. Witte discloses that the cleaning of sample conduits with steam is well known in the art, as is the direction of wash fluids to the waste site through a series of valves. In column 4, lines 20-35, Witte teaches that it is useful to transport biofluids through the valve and conduit system in order to drain the biofluid to a waste discharge (Figure 2:62).

Newberg and Witte are analogous art because they are from the same field of endeavor regarding the aseptic sampling of a biofluid.

At the time of the invention, it would have been obvious to add a trap structure to the sampling conduit in the invention disclosed by Newberg. A trap would allow for efficient collection of biofluids and wash fluids, and would help to isolate the outlet valve and biofluidic process site during cleaning procedures and wash fluid evacuation. In column 4, lines 35-45, Witte teaches that traps can be constructed to be self-draining in order to guide the cleaning agent from the system and disallow fluid from accumulating within the sampling conduit. Trapping systems are beneficial in controlling fluid flow during sterilization and waste drainage operations, as well as during biofluid sampling.

With respect to claim 27, Newberg and Witte disclose the method set forth in claim 26 as set forth in the 35 U.S.C. 103 rejection above. In addition, Newberg discloses in column 3, lines 47-54 that cleaning is conduced before collecting each sample.

With respect to claims 28 and 29, Newberg and Witte disclose the method set forth in claim 26 as set forth in the 35 U.S.C. 103 rejection above. Both Newberg and Witte teach that aseptic conditions within the sampling systems are maintained, and that the sampling conduit is fully sterilized before fluids are drawn from the source site. Merriam-Webster Online states that to sterilize means to free from living organisms and to deprive of the power of reproducing. Therefore, the cleaning methods proposed by Newberg and Witte therefore intrinsically must reduce the number of bacterial colony forming units per milliliter of rinse water to less than about 100, and reduce macromolecule contamination in rinse water to less than about 1 part per million. It would have been obvious for Newberg and Witte to pursue comprehensive sterilization methods in order to insure that the integrity of delivered sample is maintained during transportation.

With respect to claims 36 and 37, Newberg and Witte disclose the method set forth in claim 26 as set forth in the 35 U.S.C. 103 rejection above. In addition, Newberg teaches that the sampling conduit may include a probe (Figure 2:20) for sensing conditions within the apparatus. In column 10, lines 26-53, Newberg states that the probe is able to determine when there is a problem by comparing a profile of system conditions when the system is operating correctly with profiles when various components of the system fail. In this way, the disclosed pressure probes

(a differential pressure flowmeter, for example) could intrinsically be used to sense fluid flow direction in order to monitor for backflow conditions while the biofluid sites are isolated. It would have been obvious to use Newberg's probe to detect backflow because backflow is a dangerous source of contamination typical to many valve structures. It would have been critical to alter the operation of the sampling system upon detection of backflow conditions in order to maintain sample sterility.

2) Claims 26-29, 36, 37 and 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newberg (US 5296197) in view of Witte (US 5948998) and Rutherford (US 5075905).

As indicated in the 35 U.S.C. 103 rejection above, it is believed that Newberg and Witte disclose all of the limitations presented in claim 26. However, if, for the sake of argument, the trap disclosed by Witte does not meet the limitations regarding the placement of the waste valve in relation to the sampling conduit, then the claims are still rejected in view of the Rutherford reference.

Rutherford discloses a method of collecting a fluid from a source (Figure 1:11) through a sampling conduit. The sampling conduit comprises a low region that creates a trap (Figure 1:13). Fluids present at the trap can be moved to a waste container (Figure 1:22) using a waste valve (Figure 1:21). This is disclosed in column 2, lines 18-54.

Newberg, Witte and Rutherford are analogous art because they are from the same field of endeavor regarding fluid sampling methods.

At the time of the invention, it would have been obvious to ensure that the trap structure added to Newberg's sampling conduit included a low region and a waste valve coupled to the low region. This type of arrangement is beneficial because it allows fluids moving through the sampling conduit to be isolated at the trap region and drained from the trap region due to gravity. Witte teaches that traps are important components in methods pertaining to biofluid sampling, and Rutherford indicates that trap assemblies comprising waste valves coupled to low regions are well known in the art. Rutherford's trap assembly represents a viable and effective alternative to the trap structures disclosed by Newberg and Witte.

3) Claims 30-32 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newberg (US 5296197) in view of Witte (US 5948998) as applied to claim 27, and further in view of Carney (US 5771917).

With respect to claim 30, Newberg and Witte disclose the method set forth in claim 27 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly disclose that cleaning is conducted by directing wash fluid through the outlet valve into the sampling conduit.

Carney discloses an apparatus for aseptically connecting fluid processing lines. Column 3, lines 55-63 teach that a sample fluid moves into a housing (Figure 1:12) through an inlet (Figure 1:13), and is allowed to drain from the housing through a sampling conduit (Figure 1:17 and Figure 1:19) and an outlet valve (Figure 1:21). After the housing has been filled with a sample fluid and drained, the system is cleaned with a wash fluid. Carney teaches in column 4, lines 15-35 and in Figure 4 that cleaning solution enters the sampling conduit through the outlet valve.

Newberg, Witte, and Carney are analogous art because they are from the same field of endeavor regarding the ascetically transferring a fluid from a source site to a process site.

At the time of the invention, it would have been obvious to direct the wash fluids through the sampling system disclosed by Newberg and Witte in such a way that the cleaning solution would enter through the outlet valve and move into the sampling conduit. This would have been beneficial because it would have ensured that the outlet valve and all piping leading towards the process site would have been adequately sterilized. Systems that only introduce washing fluids from the inlet valve typically do not provide the means to thoroughly clean downstream components (outlet valves) because wash fluids are usually diverted to a waste site before they can contact all features of the system. Introducing wash fluid from the opposite end – the outlet valve – resolves this problem by cleaning the areas of the fluidic interface that might otherwise have been neglected.

With respect to claim 31, Newberg, Witte, and Carney disclose the method set forth in claim 27 as set forth in the 35 U.S.C. 103 rejection above. In addition, Newberg teaches in column 5, lines 43-53 that the wash solution includes steam and/or an aqueous cleaning solution.

With respect to claim 32, Newberg, Witte, and Carney disclose the method set forth in claim 27 as set forth in the 35 U.S.C. 103 rejection above. In addition, Newberg teaches in column 6, lines 25-48 and column 13, lines 9-22 that wash fluids are directed through the inlet valve (Figure 2:49) that leads to the biofluid source site. Claim 32 is interpreted to mean simply

that wash fluids move through an input valve that is connected to the source site. The claim does not clearly disclose fluids moving through the input valve in order to flow into the source site.

With respect to claim 39, Newberg and Witte disclose the method set forth in claim 36 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly disclose that the biofluid sites are isolated closing the waste valve and opening a relief valve that is located at a relief conduit, wherein the relief conduit has a proximal end coupled to the trap and a distal end coupled to the external environment.

Carney discloses a waste valve (Figure 1:62) and a relief valve (Figure 1:56) coupled to a relief conduit (Figure 1:54). Column 4, lines 26-36 teach that during the evacuation of wash fluids, the relief valve is opened to permit drainage out of the system while the waste valve optionally remains closed.

At the time of the invention, it would have been obvious to utilize a relief valve and relief conduit in the method disclosed by Newberg and Witte so that the relief conduit would be in fluid communication with the trap and the external environment. This would have allowed one to provide an additional place for waste fluids collection separate from the waste site. The motivation for doing so would have been the desire to independently collect biofluids at a site other than the aqueous cleaning liquid waste site.

4) Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Newberg (US 5296197) in view of Witte (US 5948998) as applied to claim 27, and further in view of Merten (US 6689621).

Newberg and Witte disclose the method set forth in claim 36 as set forth in the 35 U.S.C. 103 rejection above, however do not disclose the presence of a fluid flow sensing probe at the waste valve.

Merten discloses a fluid dispensing system in which a sample is drawn from a source site (Figure 1:28) to a sampling conduit (Figure 1:15) through an inlet valve (Figure 1:19B), and is transported to a plurality of process sites (Figure 1:13) through outlet valves (Figure 1:18). Waste fluids are moved through a waste valve (Figure 1:24) and conduit (Figure 1:27B), and into a waste site (Figure 1:25). Flowmeters (Figure 1:21) are provided for sensing fluid flow through the inlet, outlet, and waste valves. This is disclosed in column 9, line 12 to column 10, line 49.

Newberg, Witte, and Merten are analogous art because they are from the same field of endeavor regarding automatic sample collection and delivery devices.

At the time of the invention, it would have been obvious to monitor fluid flow through the waste valve in the method proposed by Newberg and Witte using a flow sensor. Flowmeters are beneficial because they can be used to make sure that fluids are flowing through the correct conduits at the correct time. These sensors can also be used to monitor any occurrence of backflow through the conduits. Detection of flow movement through the conduits is critical in order to ensure that the valves are working in unison to achieve a certain goal.

5) Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Newberg (US 5296197) in view of Witte (US 5948998) and Carney (US 5771917) as applied to claim 39, and further in view of Merten (US 6689621).

Newberg, Witte, and Carney disclose the method set forth in claim 39 as set forth in the 35 U.S.C. 103 rejection above, however do not disclose the presence of a fluid flow sensing probe at the relief conduit.

Merten discloses a fluid dispensing system in which a sample is drawn from a source site (Figure 1:28) to a sampling conduit (Figure 1:15) through an inlet valve (Figure 1:19B), and is transported to a plurality of process sites (Figure 1:13) through outlet valves (Figure 1:18). Waste fluids are moved through a waste valve (Figure 1:24) and conduit (Figure 1:27B), and into a waste site (Figure 1:25). Flowmeters (Figure 1:21) are provided for sensing fluid flow through the inlet, outlet, and waste valves. This is disclosed in column 9, line 12 to column 10, line 49.

Newberg, Witte, Carney, and Merten are analogous art because they are from the same field of endeavor regarding automatic sample collection and delivery devices.

At the time of the invention, it would have been obvious to monitor fluid flow through the relief conduit in the method proposed by Newberg, Witte, and Carney using a flow sensor. Although Merten does not expressly disclose a relief conduit, Merten does emphasize the importance of equipping all fluid flow conduits with detectors. Since Merten teaches the inclusion of flow sensors at the inlet, outlet, and waste valves, it would have been obvious to include a similar device to monitor the relief conduit, or any additional conduits not expressly disclosed by Merten, as well. Flowmeters are beneficial because they can be used to make sure that fluids are flowing through the correct conduits at the correct time. These sensors can also be used to monitor any occurrence of backflow through the conduits. Detection of flow movement through the conduits is critical in order to ensure that the valves are working in unison to achieve a certain goal.

6) Claims 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newberg (US 5296197) in view of Witte (US 5948998), Carney (US 5771917), and Merten (US 6689621) as applied to claim 40, and further in view of North, Jr (US 5395588).

Newberg, Witte, Carney, and Merten disclose the method set forth in claim 40 as set forth in the 35 U.S.C. 103 rejection above, however do not disclose excluding particulate contaminants from entering the relief conduit by employing a filter selected to remove particulates having a diameter of at least 0.2 μm. An overflow reservoir at the relief conduit is not expressly disclosed.

North, Jr. discloses a system for controlling the transport of biofluids from source site (Figure 1:14) to a process site (Figure 1:16). Column 4, lines 24-53 teach that a waste reservoir connected to a waste conduit is provided for collecting discharged fluids. Column 5, lines 5-12 indicate that relief conduits stemming from the waste reservoir are used in conjunction with vent filters to remove particulates having a diameter of at least 0.2 μm.

Newberg, Witte, Carney, Merten, and North, Jr. are analogous art because they are from the same field of endeavor regarding the sampling systems designed for the transport of biofluids.

At the time of the invention, it would have been obvious to exclude particulate contaminants using a filter at the relief conduit disclosed in the method proposed by Newberg, Witte, Carney, and Merten. The utilization of a filter would have been beneficial in order to provide a way to clean the waste stream from harmful agents before it is expelled from the system. This would clearly lead to increases in safety when handling the waste fluids, and would

create a waste product that could be more easily disposed. It would have further been obvoius to collect the waste fluids moving through the filtered relief conduit in an overflow reservoir. North, Jr. teaches in column 5, lines 10-12 that reservoirs prevent spillage and allow for the fluids to be easily handled. Collection in a reservoir is a safe and more environmentally sound practice than many alternatives, such as simply allowing the waste products to leak into the immediate surroundings.

7) Claims 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newberg (US 5296197) in view of Witte (US 5948998) as applied to claim 26, and further in view of Gerard (US 20020170364).

Newberg and Witte disclose the method set forth in claim 26 as set forth in the 35 U.S.C. 103 rejection above, however do not disclose that the inlet and outlet valves are located at the same height, that the trap is located at a lower elevation than the valves, or that biofluids are drained from the lowest point of the trap.

Gerard discloses a sampling apparatus designed to facilitate the movement of a fluid sample from a source site through an inlet valve (Figure 1:2) and sampling conduit (Figure 1:3). Outlet valves (Figure 2:15 and Figure 2:16) are provided for moving fluids into a process site (Figure 1:13). A trap (Figure 1:6) is located lower than the inlet and outlet valves, and assists in the removal of fluids at its lowest point (Figure 1:9). This is disclosed in paragraph [0013]. It is apparent from Figure 1 that the trap is lower than the valves by at least 3 times the inside diameter of the conduit. The sample conduit 3 could intrinsically be easily manipulated in order to bring the inlet valve more in line with the elevation of the outlet valves.

Newberg, Witte, and Gerard are analogous art because they are from the same field of endeavor regarding fluidic interfaces that facilitate the transfer of fluids from a source site to a process site.

At the time of the invention, it would have been obvious to create a trap at a substantially lower elevation than the inlet and outlet valves disclosed in the method proposed by Newberg and Witte. This would have allowed one to more easily and efficiently collect biofluids or wash fluids, and then drain them to a waste site using gravitational forces. If the trap is located above the sampling conduit, then pumps and extra equipment must be provided in order to expel the fluids from the system, which results in a more complicated and costly operation.

8) Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Newberg (US 5296197) in view of Witte (US 5948998), Carney (US 5771917), Merten (US 6689621), and North, Jr (US 5395588).

Newberg discloses a method for aseptically sampling a biofluid comprising automatically collecting a biofluid sample by opening an inlet valve (Figure 2:2) at a biofluid source site (Figure 1:53). The sample is directed to a biofluid process site (Figure 2:94) by opening an outlet valve (Figure 2:93) coupled to the process site. A waste valve (Figure 2:97), coupled to a sampling conduit (Figure 2:14) and a waste site (Figure 2:98), is closed to ensure that the sample moves to the process site. This is disclosed in column 3, lines 20-46, column 6, lines 34-48, and column 10, lines 54-62. The biofluid sites are isolated by closing the inlet and outlet valves (column 13, lines 8-37) when the waste valve is opened. Column 5, line 43 to column 6, line 33 teach that the sampling conduit is cleaned before sample collection by directing a wash fluid

through the inlet valve and subsequently through the waste valve to the waste site. In column 12, lines 19-52, Newberg teaches that all the valves and system operations are automatically regulated by a computer control means. Newberg teaches that aseptic conditions within the sampling system is maintained, and that the sampling conduit is fully sterilized before fluids are drawn from the source site. Merriam-Webster Online states that to sterilize means to free from living organisms and to deprive of the power of reproducing. Therefore, the cleaning methods proposed by Newberg therefore intrinsically must reduce macromolecule contamination in rinse water to less than about 1 part per million. Newberg, however, does not expressly disclose a trap located at the sampling conduit and fluidly connected to the waste valve, that biofluid is drained from the sampling conduit to the waste site, that a relief conduit and valve are provided, that monitoring for backflow at the relief conduit occurs, or that a filter is provided for removing particulates at the relief conduit.

Witte discloses a sampling device for taking sterile samples of a biological fluid. In column 1, line 13 to column 2, line 10 and in Figure 1, Witte discloses that it is well known in the art to draw a sample through a sampling conduit from a biofluid source site to a biofluid process site (Figure 1:14). Multidirectional valves (Figure 1:24) serving as both outlet valves and waste valves are also well known in the art, and, according to Figure 1, are capable of either directing fluids to the biofluid process site or to a waste site. A trap (Figure 1:36) is provided in connection with the sampling conduit and in fluid communication with a waste site. Witte discloses that the cleaning of sample conduits with steam is well known in the art, as is the direction of wash fluids to the waste site through a series of valves. In column 4, lines 20-35,

Witte teaches that it is useful to transport biofluids through the valve and conduit system in order to drain the biofluid to through a waste discharge (Figure 2:62).

Carney discloses an apparatus for aseptically connecting fluid processing lines. Carney's apparatus includes a waste valve (Figure 1:62) and a relief valve (Figure 1:56) coupled to a relief conduit (Figure 1:54). Column 4, lines 26-36 teach that during the evacuation of wash fluids, the relief valve is opened to permit drainage out of the system while the waste valve optionally remains closed.

Merten discloses a fluid dispensing system in which a sample is drawn from a source site (Figure 1:28) to a sampling conduit (Figure 1:15) through an inlet valve (Figure 1:19B), and is transported to a plurality of process sites (Figure 1:13) through outlet valves (Figure 1:18). Waste fluids are moved through a waste valve (Figure 1:24) and conduit (Figure 1:27B), and into a waste site (Figure 1:25). Flowmeters (Figure 1:21) are provided for sensing fluid flow through the inlet, outlet, and waste valves. This is disclosed in column 9, line 12 to column 10, line 49. Although Merten does not expressly disclose a relief conduit, Merten does emphasize the importance of equipping all fluid flow conduits with detectors. Since Merten teaches the inclusion of flow sensors at the inlet, outlet, and waste valves, it would have been obvious to include a similar device to monitor the relief conduit, or any additional conduits not expressly disclosed by Merten, as well.

North, Jr. discloses a system for controlling the transport of biofluids from source site (Figure 1:14) to a process site (Figure 1:16). Column 4, lines 24-53 teach that a waste reservoir connected to a waste conduit is provided for collecting discharged fluids. Column 5, lines 5-12

indicate that relief conduits stemming from the waste reservoir are used in conjunction with vent filters to remove particulates having a diameter of at least 0.2 μm.

At the time of the invention, it would have been obvious to combine Witte, Carney, Merten, and North, Jr. with the method proposed by Newberg in order to provide an improved fluid extraction means. The inclusion of a trap would allow for efficient collection of biofluids and wash fluids, and would help to isolate the outlet valve and biofluidic process site during cleaning procedures and wash fluid evacuation. In column 4, lines 35-45, Witte teaches that traps can be constructed to be self-draining in order to guide the cleaning agent from the system and disallow fluid from accumulating within the sampling conduit. Trapping systems are beneficial in controlling fluid flow during sterilization and waste drainage operations, as well as during biofluid sampling. The addition of the relief conduit in fluid communication with the trap and the external environment would have provided an additional place for waste fluid to be collected separate from the waste site. This would have been advantageous because the relief conduit would allow one to independently collect sample biofluids at a reservoir separate from the waste site. The utilization of a filter at the relief conduit would have been beneficial in order to provide a way to clean the waste stream from harmful agents before it is expelled from the system. This would clearly lead to increases in safety when handling the waste fluids, and would create a waste product that could be more easily disposed.

9) Claims 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Newberg (US 5296197) in view of Witte (US 5948998), Carney (US 5771917), Merten (US 6689621), North, Jr (US 5395588) and Rutherford (US 5075905).

As indicated in the 35 U.S.C. 103 rejection above, it is believed that Newberg, Witte, Carney, Merten and North Jr. disclose all of the limitations presented in claim 46. However, if, for the sake of argument, the disclosed trap does not meet the limitations regarding the placement of the waste valve in relation to the sampling conduit, then the claims are still rejected in view of the Rutherford reference.

Rutherford discloses a method of collecting a fluid from a source (Figure 1:11) through a sampling conduit. The sampling conduit comprises a low region that creates a trap (Figure 1:13). Fluids present at the trap can be moved to a waste container (Figure 1:22) using a waste valve (Figure 1:21). This is disclosed in column 2, lines 18-54.

Newberg, Witte, Carney, Merten, North Jr. and Rutherford are analogous art because they are from the same field of endeavor regarding fluid sampling methods.

At the time of the invention, it would have been obvious to ensure that the trap structure added to Newberg's sampling conduit included a low region and a waste valve coupled to the low region. This type of arrangement is beneficial because it allows fluids moving through the sampling conduit to be isolated at the trap region and drained from the trap region due to gravity. Witte teaches that traps are important components in methods pertaining to biofluid sampling, and Rutherford indicates that trap assemblies comprising waste valves coupled to low regions are well known in the art. Rutherford's trap assembly represents a viable and effective alternative to the trap structures disclosed by Newberg and Witte.

Response to Arguments

Applicant's arguments filed 06 April 2006 have been fully considered but they are not persuasive.

Applicant's principle arguments are

Claims 26 and 46 are patentable. Applicant has clearly defined the trap as "a portion of the sampling conduit extending from the inlet valve to the outlet valve, and the waste valve is coupled to a low region of the trap." The steam trap disclosed by Witte is not a portion of the sampling conduit and the sample does not flow through the trap.

In response to Applicant's arguments, please consider the following comments.

Newberg and Witte are combined to reject the claims based on 35 U.S.C. 103. Newberg discloses a sample conduit through which sample fluid and cleaning fluid are moved. Witte is simply relied upon for teachings that indicate that it is known in the art to supply a trap at the sampling conduit as a means by which to move fluids to a waste site. Witte discloses in Figure 1 a trap assembly and a waste valve coupled to a low region of the trap.

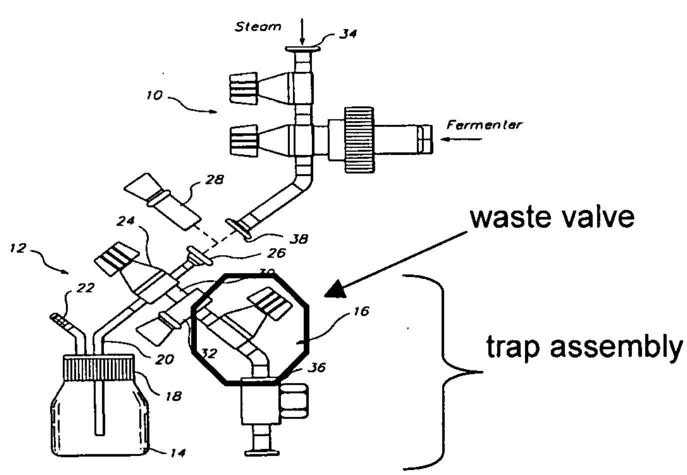

FIG. 1 PRIOR ART

Witte also discloses that it is possible to move sample fluid through the conduit to a waste site. The trap is considered to be part of the sampling conduit because the structures are in fluid communication with each other, and because sample fluids are moved through the trap. When these principles are applied to the existing structure proposed by Newberg, one is left with a trap assembly that is part of a sample conduit and capable of moving sample and wash fluid to the waste site.

Applicant is encouraged to positively recite the structural features that distinguish the trap assembly from the prior art, most notably its "U" shape.

Please note additional rejections of claims 26 and 46 made with Rutherford (US 5075905) as a supporting reference.

Allowable Subject Matter

Claims 49-51are allowed.

Claims 33-35 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The Kennedy (US 6254060) reference represents the closest prior art in that it discloses a double gate valve that could be implemented as either an inlet or outlet valve in the method proposed by Newberg, Witte, and Carney. However, the valve as disclosed by Kennedy would not be able to direct fluids through the sample conduit as well as toward the waste site. Kennedy does not disclose a single valve unit comprising two coupled three-way valves.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Matt Bauer

NAB

WILLIAM H. BEISNER
PRIMARY EXAMINER
GROUP 1744